

EXHIBIT D

Charles Hanes, II, M.D.

1 UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4
IN RE: ETHICON, INC., * MASTER FILE NO. 2:12-MD-02327
5 PELVIC REPAIR SYSTEM * MDL 2327
PRODUCTS LIABILITY * JOSEPH R. GOODWIN
6 LITIGATION * U. S. DISTRICT JUDGE

7
THIS DOCUMENT RELATES TO ALL CASES.

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14 The deposition of CHARLES HANES, II, M.D.,
15 taken at Helmsing, Leach, Herlong, Newman &
16 Rouse, 150 Government Street, Suite 200,
17 Mobile, Alabama, on the 12th day of July, 2019,
18 commencing at approximately 9:30 a.m.

Charles Hanes, II, M.D.

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17

LOIS ANNE ROBINSON, RPR, RDR, CRR

18 COURT REPORTER

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Charles Hanes, II, M.D.

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Charles Hanes, II, M.D.

1 (EXHIBITS 1 THROUGH 6 WERE
2 MARKED FOR IDENTIFICATION.)

3 CHARLES HANES, II, M.D.,
4 the witness, after having first been
5 duly sworn to tell the truth, the whole truth,
6 and nothing but the truth, was examined and
7 testified as follows:

8 EXAMINATION

9 BY MS. WATKINS:

10 Q Good morning, Doctor.

11 A Good morning.

12 Q Can you hear me okay?

13 A I can.

14 Q Okay. As we discussed before we went
15 on the record, I am attending by phone, so if at
16 any point you cannot hear me, will you please let
17 me know?

18 A I certainly will.

19 Q Okay. And if you don't understand any
20 of my questions, will you please let me know?

21 A Certainly.

22 Q Okay. And you've done a report setting
23 forth your opinions regarding the Prolift and the
24 Prolift + M; correct?

Charles Hanes, II, M.D.

1 A Correct.

2 Q At this time, do you have any changes

3 or additions to your Prolift report?

4 A Not at this point. Yes.

5 Q Okay. And you've also done a report

6 setting forth your opinions on the TVT, the

7 TVT Obturator, the TVT EXACT, and the TVT

8 ABBREVO; correct?

9 A Correct.

10 Q And do you have any changes or

11 additions to that report at this time?

12 A No.

13 Q Okay. And have you seen the deposition

14 notice for your deposition here today?

15 Yes.

16 MS. WATKINS:

17 Q And, Madam Court Reporter, Miss Lois,

18 have we marked that as an exhibit yet?

19 THE COURT REPORTER:

20 Not yet. I'll make it Number 7.

21 (EXHIBIT NUMBER 7 WAS

22 MARKED FOR IDENTIFICATION.)

23 MS. WATKINS:

24 Number 7.

Charles Hanes, II, M.D.

1 Q The court reporter has marked the
2 Notice of Deposition as Exhibit 7. And have you
3 seen Exhibit A, Doctor, to that notice, which is
4 on page 6 that's titled "Schedule A"?

5 MR. BARTON:

6 And, Diane, just for the record, we did
7 file, I think, objections and responses to the
8 deposition notice and documents requested, and
9 you should have received that. Did you receive
10 that?

11 MS. WATKINS:

12 I believe so. Understood.

13 MR. BARTON:

14 Okay. Great.

15 A So, yes. I'm looking at page 6.

16 MS. WATKINS:

17 Q Okay. Have you brought the responsive
18 materials with you here today?

19 A Yes.

20 Q Okay. And what have you brought to the
21 deposition?

22 A We brought a CV, the general documents,
23 the invoice, and the -- yeah, the copy of the
24 general reference materials.

Charles Hanes, II, M.D.

1 Q Okay. And, for the record, I
2 believe -- and correct me if I'm wrong, please --
3 that we've marked the flash drive. It was
4 Exhibit 1.

5 A Yes.

6 Q Is that correct?

7 A Was that Exhibit 1? Yes.

8 Q And does the flash drive contain the
9 reliance materials for your Prolift and TVT
10 reports?

11 A It appears to, yes.

12 Q Okay. And have we marked your invoice
13 as Exhibit 2?

14 A Yes.

15 Q Okay. And I want to talk for a minute
16 about the invoice. The invoice appears to have
17 two line items, one pertaining to your Prolift
18 report and one pertaining to your TVT report.
19 Correct?

20 A Correct.

21 Q And the first line item lists 5-11
22 through 5-17, preparation of TVT report, 25.4
23 units, \$450 cost per unit, which equals
24 \$11,430.00; correct?

Charles Hanes, II, M.D.

1 A Yes.

2 Q Okay. I assume the units are the hours
3 spent? Is that correct?

4 A That is correct.

5 Q And does the preparation of the TVT
6 report include reviewing materials or simply
7 drafting the report?

8 A Reviewing materials.

9 Q Okay. And drafting it?

10 A Correct.

11 Q Okay. And, then, so I assume the 5-11
12 through 17, was that May 11th through May 17th
13 working on it?

14 A Yes.

15 Q Okay. And then the next line item is
16 May 17th through 26th, preparation of Prolift
17 report. And, so, did you spend 18.4 hours
18 reviewing materials and preparing the Prolift
19 report?

20 A I did.

21 Q Okay. And that cost per unit for both
22 of those reports was \$450 per hour?

23 A Correct.

24 Q Okay. So for Prolift, the total amount

Charles Hanes, II, M.D.

1 was \$8,280.00; correct?

2 A Correct.

3 Q So for your TVT -- or for the TVT time,
4 referring to the TVT family of products that
5 you've included in your report, for the TVT and
6 Prolift report, your review of materials and then
7 drafting the report, the --

8 Well, strike that.

9 The total amount that you've spent for
10 those two reports is contained within those
11 invoices. Is that -- or that invoice. Is that
12 correct?

13 A That is correct.

14 Q Okay. And, then, is your CV, which
15 we've marked as Exhibit 3, current as of today?

16 A Yes, it is.

17 Q Okay. And I noticed -- we noticed
18 your -- or -- excuse me -- we marked your general
19 materials list as Exhibit 4, but I was provided
20 with a supplemental materials list a couple days
21 ago. Have you been provided with that
22 supplemental list?

23 A I'm not aware of that.

24 Q Okay. And does the general materials

Charles Hanes, II, M.D.

1 list that you have, marked as Exhibit 4, apply to
2 both the Prolift report and the TVT report?

3 A I believe so, yes.

4 Q Okay. When were you first contacted by
5 Ethicon's counsel regarding serving as a general
6 causation expert in the Ethicon litigation?

7 A It was -- I would think it was either
8 right at the end of April or the beginning of
9 May.

10 Q Of 2018?

11 A Yes. No. 2019.

12 Q Okay. And we talked a little bit about
13 your invoice. Have you or are you going to bill
14 Ethicon anything in addition to the invoice that
15 you've marked as Exhibit 2 for your services as a
16 general causation expert in the Ethicon
17 litigation?

18 A I'll bill them for our time today and
19 preparation for this deposition.

20 Q Okay. How much time did you spend
21 preparing for the deposition?

22 A Three hours.

23 Q And when was that?

24 A Yesterday evening, or afternoon.

Charles Hanes, II, M.D.

1 Q And what did you do to prepare?

2 A Mr. Barton and I spent some time
3 discussing the materials.

4 Q Did you meet with Mr. Barton for three
5 hours?

6 A Yes.

7 Q Aside from meeting with Mr. Barton and
8 reviewing your reports, did you review anything
9 else?

10 A No.

11 MS. WATKINS:

12 Madam court reporter, if you don't mind
13 marking what I've emailed to you which is titled
14 "Supplemental General Materials List" -- it has
15 Dr. Hanes' name at the top -- as Exhibit 8, I
16 would appreciate it, when you get a moment.

17 THE COURT REPORTER:

18 I do not have one named that, I don't
19 think. I have other things, but I don't have
20 that.

21 MS. WATKINS:

22 Okay. That's fine.

23 Q Okay. Dr. Hanes, aside from meeting
24 with Dr. Barton -- excuse me -- Mr. Barton

Charles Hanes, II, M.D.

1 yesterday, have you had communications with
2 counsel for Ethicon regarding this litigation?

3 A Regarding these general reports or --
4 Be more -- what -- I'm not sure I
5 understand.

6 Q Well, you said your first contact was,
7 I believe, in April of May of 2019. And, at that
8 time, who was your contact person as far as
9 Ethicon's attorney?

10 A Jordan Walker.

11 Q Okay. And did you have any phone
12 conferences with Jordan Walker about the general
13 expert reports that you were going to be
14 drafting?

15 A No, not --

16 I mean, we've talked subse- -- we've
17 talked a couple of times in the -- in the course
18 of this whole process. But at the time of
19 initial contact, it was just a request for me to
20 do the general reports, and that -- that was it.

21 Q Okay. Aside from the work that
22 we've -- you've done for the general causation
23 expert report, have you done any other work for
24 the Ethicon transvaginal mesh litigation?

Charles Hanes, II, M.D.

1 A Yes. I've done some case-specific
2 reports.

3 MR. BARTON:

4 And, Diane --

5 MS. WATKINS:

6 Q Do you know how many case-specific
7 reports you've done?

8 MR. BARTON:

9 Diane, excuse me for a second, since
10 you can't see me. Let me just interject an
11 objection to "work for." I mean, he's a paid
12 outside --

13 MS. WATKINS:

14 Understood. I can rephrase my --

15 MR. BARTON:

16 -- consultant.

17 MS. WATKINS:

18 I'll withdraw my question.

19 MR. BARTON:

20 Okay. Thank you.

21 MS. WATKINS:

22 Q Doctor, it's my understanding that you
23 have been retained in certain cases to do
24 case-specific reports in the Ethicon litigation.

Charles Hanes, II, M.D.

1 Is that correct?

2 A Yes.

3 Q And how many cases have you been
4 retained to do case-specific expert reports in
5 the Ethicon litigation?

6 A I don't know the exact number, but it's
7 probably close to a dozen, about a dozen.

8 Q Have you been deposed in those cases?

9 A I've been deposed on one.

10 Q Do you know the name of that case?

11 MR. BARTON:

12 Aldridge?

13 THE WITNESS:

14 Aldridge. Yeah. I think that's the --

15 MS. WATKINS:

16 Q Is that Margaret Aldridge? Does that
17 ring a bell?

18 A I can't remember.

19 Q Okay. The only reason I asked is
20 because that happened to be my case, and it was
21 an Ethicon case.

22 Have you been deposed as a treating
23 physician in any of the Ethicon transvaginal mesh
24 cases?

Charles Hanes, II, M.D.

1 A No.

2 MR. BARTON:

3 Well --

4 THE WITNESS:

5 Oh, wait. Excuse me.

6 MS. WATKINS:

7 Q You said you have been deposed in the

8 Aldridge case?

9 MR. BARTON:

10 Diane, let me interrupt you, just to

11 help both of you, to be sure you're not

12 misunderstanding each other. You asked him if he

13 had ever been deposed as a treater?

14 THE WITNESS:

15 Treating physician.

16 MS. WATKINS:

17 Yes.

18 MR. BARTON:

19 As a treating physician. And you have

20 been deposed as an implanter.

21 MS. WATKINS:

22 Sorry. No. I'll rephrase.

23 MR. BARTON:

24 Right?

Charles Hanes, II, M.D.

1 MS. WATKINS:

2 Q But you've been deposed in the Aldridge
3 case; is that correct?

4 A That's correct. And we're -- we're
5 discussing. I may have been deposed as a
6 treating physician, and I can't remember.

7 MR. BARTON:

8 Diane, I believe Dr. Hanes has been --

9 And I don't want us to trip up on
10 words. In our shop, we often refer to the
11 doctors wearing different hats as maybe an
12 implanter, an explanter, or just a treater --

13 MS. WATKINS:

14 Right.

15 MR. BARTON:

16 -- a treater being someone who didn't
17 do surgery, didn't do an implant or an explant
18 but just a treating physician. So I don't know
19 if Dr. Hanes is confused with that language or
20 y'all are on the same page or not.

21 But I think Dr. Hanes may have been
22 deposed in this litigation as an implanter years
23 ago.

24 MS. WATKINS:

Charles Hanes, II, M.D.

1 Okay. Fair enough.

2 MR. BARTON:

3 But you need to clarify that with him.

4 MS. WATKINS:

5 Some people do interpret the word
6 "treater" differently.

7 Q Doctor, as an implanter or explanter or
8 treater of a transvaginal mesh plaintiff, have
9 you been deposed for purposes of litigation?

10 A I honestly can't remember. I'm sorry.

11 Q Okay. Fair enough.

12 And, Doctor, you are -- you know, I
13 think Ethicon's counsel may have informed you.
14 If you do not remember or you do not know the
15 answer, you are able to say that.

16 A Okay. Yeah.

17 Q I appreciate your answer, though.

18 And we talked a little bit about your
19 invoice. Is your fee schedule for review and
20 preparation of reports \$450 per hour?

21 A Yes.

22 Q And -- and is that the same price for
23 deposition testimony?

24 A Yes.

Charles Hanes, II, M.D.

1 Q And do -- what about trial testimony?

2 A Thus far, I've not been to trial. But

3 I think -- I think that the charge is \$5,000 per

4 day.

5 Q Okay. Have you ever testified at any

6 trial for any purpose, meaning not even -- not

7 limiting it to transvaginal mesh. Any trial.

8 A I don't believe so, no.

9 Q Okay. And is your charge for

10 consultation and meeting with counsel \$450 per

11 hour?

12 A Yes.

13 Q So aside from your meeting with

14 Mr. Barton yesterday, the invoice that we've

15 marked as Exhibit 2 is what you've billed for the

16 Ethicon litigation thus far. Is that correct?

17 A For the preparation of the general

18 reports.

19 MR. BARTON:

20 In this case.

21 THE WITNESS:

22 Yeah, in this case.

23 MS. WATKINS:

24 Q Right.

Charles Hanes, II, M.D.

1 And, then, aside from any meeting with
2 Mr. Barton, have you done anything else for the
3 Ethicon litigation that you intend to bill for?

4 A The case-specific reports, as -- you
5 know, if any further arise.

6 Q Okay. And if there's moments of
7 silence, Doctor, it's just because I'm going
8 through my outline and crossing things off. So
9 just as an FYI. I have not checked out. Just
10 notes on my outline.

11 Have you been paid for the amount that
12 you've billed on the invoice that we've marked as
13 Exhibit 2?

14 A Not to date.

15 Q Okay. Have you served as an expert
16 witness for any transvaginal mesh manufacturer?

17 A No.

18 Q And is that true with respect to
19 case-specific as well?

20 A Correct.

21 Q Have you been deposed as a treater,
22 implanter, or explanter in any transvaginal mesh
23 case against a manufacturer other than Ethicon?

24 A No, I have not.

Charles Hanes, II, M.D.

1 Q Okay. Have you given a deposition in a
2 transvaginal mesh case prior to today, aside from
3 the one that you mentioned, which I believe is
4 Aldridge?

5 A No, I don't believe so.

6 MR. BARTON:

7 What you said is you can't remember.

8 THE WITNESS:

9 Yeah. I can't be certain about that,
10 but I can't recall another one.

11 MS. WATKINS:

12 Q Have you talked to any Ethicon
13 employees in conjunction with forming your
14 opinions in the transvaginal mesh litigation?

15 A No, I have not.

16 Q Aside from your expert work for
17 purposes of the transvaginal mesh litigation,
18 have you been a consultant for Ethicon?

19 A I have.

20 Q Okay. And Lois will have some
21 consulting agreements in front of her.

22 And, Lois, if you don't mind marking
23 those. I believe that there are five consulting
24 agreements that we could locate. So if you don't

Charles Hanes, II, M.D.

1 mind, Lois, start off with the earliest, which is
2 the February 2007 consulting agreement, and
3 marking those 9, 10, 11, 12, 13.

4 (EXHIBITS 8, 9, 10, 11, AND 12
5 WERE MARKED FOR IDENTIFICATION.)

6 MS. WATKINS:

7 Q Doctor, the earliest consulting
8 agreement that we could find was February 2007.
9 Do you believe that that was when you first
10 started working as a consultant for Ethicon or do
11 you believe that it might be sooner than that?

12 A I think it was -- I think it was sooner
13 than that.

14 Q Okay. When do you think you first
15 became a consultant for Ethicon?

16 A I think it was 1999 or possibly 2000.
17 But it was right -- right in that neighborhood.

18 Q In '99 or 2000, what was your role as a
19 consultant for Ethicon?

20 A I became a preceptor for instructing
21 physicians on the use of the TVT.

22 Q The TVT retropubic?

23 A Yes.

24 Q And do you recall how much -- what the

1 **compensation agreement was at that time?**

2 A Diane, I think -- I think it was a
3 thousand dollars per physician trained.

4 **Q Did the physicians come to you and**
5 **observe you doing the procedure?**

6 A They came to me, and they -- we did a
7 multiple kind of training episode. We had access
8 to a cadaver lab, which we took them to, and
9 instructed them on the use, in the cadaver
10 setting, and then we went and they watched live
11 surgery. And then we had a didactic along with
12 that.

13 **Q Was that there in Mobile or was that in**
14 **New Jersey or elsewhere?**

15 A No. That was in Mobile.

16 **Q Okay.**

17 A And we used the University of South
18 Alabama Medical Center Department of Anatomy for
19 the cadaver lab.

20 **Q Okay. So from 1999 to 2000 on, did you**
21 **have an annual contract with Ethicon up until a**
22 **certain period of time, to your knowledge?**

23 A Yeah. I think it was an annually
24 renewable contract.

Charles Hanes, II, M.D.

1 Q As a preceptor?

2 A Yes.

3 Actually, it says on here -- it says on
4 this one I'm looking at "Extend for a period of
5 one year with automatic renewals for an
6 additional two years." So I guess the contract
7 was rewritten every two or three years.

8 Q Okay. So when was the last time you
9 served as a preceptor for Ethicon?

10 A I think it was in 2012. Maybe 2011,
11 but right in that...

12 Q Okay. So is it your memory that from
13 1999 or 2000 to 2011 or 2012, you were a
14 preceptor for Ethicon during those years?

15 A Yes.

16 Q And aside from the TVT retropubic, are
17 there any other products that you were a
18 preceptor for?

19 A I became -- as soon as they added the
20 TVT-O, then I was a preceptor for that. And then
21 once the Prolift products came on board, I became
22 a preceptor for them as well. It wasn't -- it
23 wasn't immediately after their introduction, but
24 it was maybe a year after they were on the

Charles Hanes, II, M.D.

1 market, or thereabouts.

2 Q Okay. Were you a preceptor for the TVT

3 EXACT?

4 A I don't remember exactly when the EXACT

5 came on board. But if it came on board before

6 2011, then I was.

7 Q Okay. And, then, what about the

8 TVT ABBREVO?

9 A Yes.

10 Q And what about the TVT SECUR?

11 A No. I never -- I never was a preceptor

12 for that.

13 Q Were you a preceptor for the

14 Prolift + M?

15 A Yes.

16 Q And did your compensation increase from

17 the thousand dollars per doctor, which was your

18 memory, from 2000 or -- excuse me -- 1999, 2000,

19 to 2011, 2012, did this increase over time?

20 A No, it did not.

21 Q Okay. I want to look a little bit

22 about the consulting agreements that we were able

23 to find. Obviously, there are totally some of

24 them out there that we couldn't find. But the

Charles Hanes, II, M.D.

1 first is dated February 9th, 2007, which we've
2 marked as Exhibit 9, I believe.

3 A Yes.

4 Q Do you have that in front of you,
5 Doctor?

6 A I do.

7 Q Okay. If you don't mind just turning
8 to --

9 In the bottom right corner, you'll see
10 that the parties have marked these documents with
11 what we call Bates numbers, and the last three
12 are 169.

13 A 169?

14 Q Uh-huh.

15 And let me know, please, when you get
16 to that page.

17 A I don't see the Bates number. Do you?

18 MR. BARTON:

19 Diane, these copies do not appear to be
20 Bates-labeled.

21 MS. WATKINS:

22 Really.

23 MR. BARTON:

24 Yeah. Sorry about that, but I don't

Charles Hanes, II, M.D.

1 see that.

2 MS. WATKINS:

3 The bottom right corner?

4 THE WITNESS:

5 No.

6 MS. WATKINS:

7 They're the same ones I sent the court
8 reporter, the same ones I printed out.

9 THE COURT REPORTER:

10 They're the ones I printed out.

11 THE WITNESS:

12 Which page do you want me to get to?

13 MS. WATKINS:

14 Q Well, it's the --

15 MR. BARTON:

16 Well, maybe they're in the lower left.

17 THE WITNESS:

18 Let's see.

19 MS. WATKINS:

20 Well, it's the -- look at the last page
21 of the consulting agreement dated February 9th,
22 2007.

23 MR. BARTON:

24 I don't think that's a Bates label.

Charles Hanes, II, M.D.

1 THE WITNESS:

2 Huh-uh.

3 MS. WATKINS:

4 And the paragraph numbers are 5, 6, 7,
5 8.

6 MR. BARTON:

7 So, Diane, I don't think these have the
8 Bates-labeled numbers on them. But we may be
9 able to follow along if you just identify the
10 page you want him to look at.

11 MS. WATKINS:

12 Q Okay. Well, it's the fourth page from
13 the last.

14 A Fourth page --

15 Okay. Is that the page that's got item
16 B at the bottom?

17 Q Yes.

18 A Okay.

19 Q Okay. I'm going to ask you a little
20 bit about paragraph 8. And that paragraph
21 describes the description of services as
22 participation in the 2007 Incontinence and Pelvic
23 Floor Summit held in St. Petersburg, Florida.

24 A Okay.

Charles Hanes, II, M.D.

1 Q Do you see that, Doctor?

2 A Yes.

3 Q Do you recall attending that conference
4 in St. Petersburg, Florida?

5 A I do.

6 Q And do you recall what your role would
7 have been at that conference?

8 A The summit -- the summit meetings were
9 meetings that Gynecare put on for all of the
10 preceptors. And it was an annual meeting where
11 the preceptors came together, together with the
12 representatives from the company who were
13 specifically relegated to the -- to these
14 products, and it was a meeting -- it was a
15 meeting that was put on really to, number 1,
16 update us on any -- any developments, but number
17 2 was to provide kind of a free-flowing forum for
18 discussion on products, problems, recommendations
19 of how to improve techniques, et cetera. You
20 know, it's just a --

21 It was really a great meeting, in my
22 opinion, because it was designed to further the
23 betterment of the services that we delivered and,
24 where applicable, improve on the products.

Charles Hanes, II, M.D.

1 Q Okay. And, based on your memory, did
2 you attend the annual meeting from when you first
3 started working as a preceptor in 1999 or 2000
4 till when you last served as a preceptor in 2011
5 or 2012?

6 A I think I -- yeah. I think --
7 I can't remember a single one of those
8 summit meetings that I missed. They were --

9 Q Okay.

10 A They were very excellent meetings, and
11 I -- I really gained a tremendous amount from
12 attending them.

13 Q And you mentioned a discussion at those
14 meetings of problems. Do you recall any problems
15 that were discussed regarding the transvaginal
16 mesh product?

17 A I don't remember any generic problems.
18 I mean, you know, people would have specific
19 things that might have arisen and they would get
20 feedback on. But I don't remember anything that
21 was generic to the -- to the product, if that
22 makes sense.

23 Q Yeah.

24 Do you remember anything specific to

Charles Hanes, II, M.D.

1 **any of the products that was discussed?**

2 A Oh, gosh. You know, I remember --

3 For example, I do -- I do recall that
4 there was discussion about this whole issue of
5 mesh contracture. And that was debated. And, to
6 the best of my knowledge, nobody really had
7 any -- any knowledge or experience of having that
8 problem.

9 I think the general agreement was
10 whenever -- whenever there's a scar, there's
11 gonna be a contraction of the scar. But it was
12 not a function of the mesh. It was a function of
13 the scar.

14 So it was just never really something
15 that --

16 You know, and we were getting reports
17 like, you know, there were mesh contractures of
18 50 percent. And that was, you know, outrageous.
19 I mean, nobody, including myself, ever
20 experienced anything like that. So it just --

21 You know, there were things that came
22 up that were being reported, and, so, we would
23 discuss those and try to -- try to come to -- to
24 the bottom of it and some, you know -- just

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1 obtain the experiential evidence that we all
2 brought together as a group of experts around the
3 country.

4 Q Okay. And were, to your knowledge,
5 were all of the attendees at these conferences or
6 annual preceptors for Ethicon?

7 A Well, the -- the invited attendees,
8 yes, were. Of course, the company representative
9 attendees were there as well.

10 Q Okay. And over the course of your
11 practice, including those meetings, have you
12 formed an opinion as to whether mesh can contract
13 after proper implantation?

14 A Yeah. I don't -- I don't -- I don't
15 believe in --

16 Like I say, I mean, there is
17 contraction associated with any scar. I mean,
18 that's a property of healing and a property of
19 scar formation. But contraction beyond that norm
20 that's expected as a result of the implantation
21 of the mesh I would disagree with.

22 Q Okay.

23 A And let me go -- can I go back a
24 minute? You asked about the attendees. I mean,

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1 there were occasionally --

2 Like, I think that one time the product
3 developer, the inventor of the TVT-O,
4 Dr. de Leval, was there, and they would have
5 occasional guests like that who were, you know,
6 obviously related. They were physicians that
7 were related to the products.

8 Q Okay. Fair enough.

9 And, of course, throughout the
10 deposition, if you'd like to either supplement or
11 change an answer, feel free to do so. I
12 appreciate that.

13 And just so I have an understanding of
14 your opinion about mesh contracture or
15 contraction, is it --

16 And I'm not trying to be argumentative.
17 I just want to understand what your opinion is.

18 Is it your opinion that the mesh itself
19 does not contract; it is the scar tissue that
20 contracts?

21 A That's correct. I mean, with the --
22 with the implantation of mesh, you have tissue
23 incorporation. And, so, as that tissue is
24 incorporated and then that tissue becomes a part

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1 of the scarring that accompanies the incision,
2 then it's going to -- to contract, but, again,
3 not to any greater degree.

4 In fact, in my opinion, the tissue
5 incorporation keeps the mesh from contracting.
6 It seems inconceivable to me that the mesh could
7 contract beyond what the tissue and scarring is
8 doing simply because the integration of the
9 tissue with the mesh.

10 Q Okay. And when you attended these
11 annual Ethicon conferences, were all of the
12 products, meaning the TVT line of products and
13 the Prolift line of products, discussed?

14 A Yes.

15 Q Okay.

16 Okay, Doctor. You can set aside
17 Exhibit Number 9, and I'd like to move on to
18 Exhibit Number 10, which is a consulting
19 agreement from the same year, but it's March 1st,
20 2007. Do you have that in front of you, Doctor?

21 A Yeah. I've got -- maybe the --

22 The first one, you said, was 9, and the
23 one March 1, 2007, has the label 8 on it. So
24 that was out of order. But...

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1 Q Okay. So that's been marked Exhibit 8?

2 A Yes. And the 10 is dated 2 -- February

3 1, '09.

4 Q Okay. Okay. I appreciate that.

5 Okay. If you don't mind turning three

6 pages in, where the first couple paragraphs are

7 numbered 11 and 12?

8 A Got it.

9 Q Okay. And if you don't mind looking at

10 paragraph 12, six lines from the bottom, there is

11 a sentence that says -- that starts with "you

12 shall not."

13 A Yes.

14 Q Do you see that, Doctor? I'm just

15 going to read that into the record and ask if

16 that's something that you agreed to with respect

17 to this consulting agreement.

18 "You shall not make any representations

19 relating to Company's products or to Company's

20 clinical outcomes unless such representations

21 have been reviewed and approved in advance by

22 Company."

23 Did I read that correctly?

24 A Yes.

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1 Q Okay. I'll represent to you that in
2 each of the contracts that we've marked here
3 today, that provision is included in there. Was
4 that something you agreed to as a consultant for
5 Ethicon?

6 A Yes.

7 Q Perfect.

8 And, then, if you don't mind turning to
9 the -- it's called Exhibit A.

10 A I've got it.

11 Q It is six pages from the back.

12 Okay. And under A4, it says
13 "Preceptor/Surgical Training," and it says,
14 "Consultant shall allow visiting surgeons and
15 visiting company sales representatives to observe
16 surgical procedures involving the practice of
17 professional education training the clinical uses
18 of various Ethicon products, and to consult with
19 consultants regarding such procedures applicable
20 patient confidentiality and consent
21 requirements."

22 Do you see that?

23 A I do. But on this particular copy, it
24 does not put in -- after you said "involving the

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1 practice of the clinical uses of," but it
2 doesn't -- doesn't write in those specifics that
3 you said. And then it resumes, "and to consult
4 with consultant regarding such procedures."

5 MR. BARTON:

6 Diane, it looks like it's blank.

7 MS. WATKINS:

8 Q Okay. And, Doctor, is this the
9 preceptor training that you discussed earlier in
10 your deposition?

11 A Yeah. I believe it is.

12 Q Okay. And when you were a preceptor,
13 was that --

14 Well, strike that.

15 When you were a preceptor for Ethicon,
16 were you a preceptor for the Prolift product as
17 well as the TVT product?

18 A Yes.

19 Q And the bottom part of that paragraph
20 states, "Consultant shall allow such visits on up
21 to 15 occasions, and Company shall pay consultant
22 2,000 for each such session per eight-hour day."

23 Do you see that?

24 A Okay. Again, they didn't have -- my

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1 copy doesn't have those blanks filled in, so --

2 Q That is --

3 A \$2,000.00 for each session per

4 eight-hour day. So it didn't have \$2,000.00.

5 And I think I told you earlier it's one thousand

6 per physician. But if that's what it says, then

7 that would be. Because I can't --

8 MR. BARTON:

9 Diane, the exhibit we're looking at is

10 blank.

11 MS. WATKINS:

12 That is weird.

13 Lois, off the record real quick,

14 please.

15 (OFF THE RECORD.)

16 MS. WATKINS:

17 Q Okay. Doctor, we were off the record

18 kind of clearing up some miscommunication about

19 the agreement with Ethicon, Consultant Agreement

20 dated March 1st, 2007, and it looks like you were

21 compensated, under that agreement, \$2,000 for

22 each section of the preceptor for the Ethicon

23 products. Is that correct?

24 A Correct.

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1 Q And do you recall, on an annual basis
2 starting in 1999 or 2000 to 2012, how much you
3 were compensated by Ethicon for your consulting
4 work on an annual basis?

5 A I do not.

6 Q Do you have a ballpark?

7 A Oh, gosh. No. I really don't.

8 Q Okay. Under the terms of this March
9 2007 agreement, you were able to be compensated
10 \$2,000 for each session up to 15, which would
11 obviously be 30,000. Do you think that you would
12 have reached that 30,000?

13 A I think I would have, yes.

14 Q Okay. You can set that one aside,
15 Doctor.

16 And, then, we're now gonna move on to
17 the consulting agreement dated February 1st,
18 2009, which I thought was marked as Exhibit 11.
19 But I'm clearly off on my exhibits, I think.

20 A Yeah. It's number 10.

21 Q Okay. Thank you.

22 A And 11, Exhibit 11 is 1-25-10.

23 Q Okay. Then I'm one off on all mine.

24 Okay.

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1 And, Doctor, we could not find any
2 consulting agreement for the year 2008. Is it
3 your belief and memory that, from when you first
4 started working as a preceptor for Ethicon in
5 1999 or 2000 to 2012, you were a preceptor every
6 year?

7 A Yes.

8 Q Okay. And, so, there likely is a
9 contract out there somewhere for 2008, based on
10 your memory; is that correct?

11 A I guess, unless -- you know, in this
12 first paragraph, it says "automatic renewals for
13 two years." So I don't know if that would mean
14 that there wouldn't be another written contract.

15 Q Okay. Understood.

16 Okay. If you don't mind turning to the
17 third-to-the-last page, which my copy, in the
18 bottom right-hand corner, ends with 792. Let me
19 know when you're there, please, Doctor.

20 A Is that Exhibit A again?

21 Q It is the third-from-the-last page.
22 The bottom, in the right-hand corner, is 702, and
23 it's the fourth paragraph, under Services and
24 Fees.

Charles Hanes, II, M.D.

1 A Is that "you and company"? Is that
2 paragraph 20?

3 Q Paragraph 4. It's A4 under Exhibit A.

4 A Oh, I've gotcha. Okay. Oh, yeah.
5 Gotcha.

6 Q Okay. And this, again, discusses your
7 preceptor role with Ethicon. And just to kind of
8 circumvent additional questions, from the time
9 you served as a preceptor starting in '99 or 2000
10 to 2012, did you cover the TVT line of products
11 as well as the Prolift products as a preceptor
12 during all of those years?

13 MR. BARTON:

14 Object to the form.

15 Go ahead.

16 A I did.

17 MS. WATKINS:

18 Q Okay. And under the terms of this
19 contract, in the summer of --

20 Excuse me. Strike that.

21 Under the terms of this contract from
22 February 2009, you are to be compensated \$2,000
23 for each session for an eight-hour day up to 12.
24 Do you see that?

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1 A I do.

2 Q And do you think that you would have
3 reached that maximum of 24,000 for that year?

4 A Yes.

5 Q Okay. Let's look at the next page --

6 MR. BARTON:

7 Diane, can you hear me? This is Jim.

8 MS. WATKINS:

9 Yeah, Jim.

10 MR. BARTON:

11 Just let me interrupt for one second,
12 because I may have misunderstood. And I
13 apologize. And I apologize for interrupting if I
14 have misunderstood. But was the prior question
15 that you asked him whether he was a consultant
16 for Ethicon for the TVT family of products as
17 well as Prolift through the entire time he was a
18 consultant for Ethicon? Because I don't --

19 That wouldn't be correct. You weren't
20 a consultant for them on Prolift until it was --
21 until it was available; right?

22 THE WITNESS:

23 Yeah. Till -- yeah, till after it was
24 available. Yeah.

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1 MR. BARTON:

2 Till after it was available. And he
3 had asked and answered that previously.

4 Did I misunderstand your question and
5 his answer, Diane? I just want to be sure you're
6 not miscommunicating.

7 MS. WATKINS:

8 No, I -- that's fair. So I assume
9 we're still on the record.

10 Q So, Doctor, from the time Prolift was
11 available to when it was not available, when you
12 were serving as a preceptor, was Prolift included
13 as one of the products that you were a preceptor
14 for?

15 A Again, I would -- I would say,
16 basically, that's true. But I didn't -- I did
17 not become a preceptor for Prolift immediately
18 upon its introduction to the market. I was about
19 a year into it before I became a preceptor.

20 Q Okay. Fair enough.

21 And, then, on the consultant agreement
22 dated February 1st, 2009, if you don't mind
23 turning to the second-to-last page, at the top
24 it's paragraph 5, Advisory Board.

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1 A Yeah.

2 Q Let me know when you're there, Doctor.

3 Okay. And that states, in part,

4 "Consultant shall participate in various opinion

5 meetings organized throughout the year for

6 ProfEd," which would be Professional Ed,

7 "training."

8 Do you see that?

9 A Yes.

10 Q And it also states that "Company shall

11 pay consultant \$2,000 per eight-hour day for each

12 such meeting."

13 Do you believe that you did serve as a

14 consultant in these Professional Ed trainings for

15 \$2,000.00 per day?

16 A Yes.

17 Q And do you recall what your role would

18 be in those meetings?

19 The reason I ask, it seems to be

20 different than the preceptor paragraph.

21 A Yeah. I think it falls under two

22 categories. One -- one would be meetings that

23 were out of town in other locations where they

24 would put on a bigger meeting and invite

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1 potential user doctors to and have a large
2 cadaver lab setting, and there would be a number
3 of us preceptors who were there because of the
4 volume of the -- the volume of attendants.

5 Q Okay.

6 A So that was one aptly -- one instance
7 of that. And, then, another, I presume, by
8 ProfEd -- I'm not --

9 Well, yeah. ProfEd training. Yeah.
10 So those were training meetings. So that would
11 be it. Yeah. And there were a number of
12 locations over the years that I went to to help
13 put on those courses.

14 Q Okay. Were any of those overseas?

15 A No.

16 Q And, at the bottom of that page, the
17 very last section, "The Parties agree that the
18 compensation paid to consultant shall not exceed
19 20,000" -- strike that -- "shall not exceed
20 26,000 per year, except as may be mutually agreed
21 in writing by the parties."

22 Do you have an understanding or memory
23 of how much you would have received in 2009 with
24 respect to that 26,000?

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1 A I don't specifically, but I -- I think
2 that I probably maxed out on most of the years.

3 Q Okay. And, then, not to belabor this,
4 but we have two more that we were able to find.

5 So if you don't mind turning to the next
6 consulting agreement, which is dated

7 January 25th, 2010.

8 A Correct.

9 Q Which I think you told me we've marked
10 as Exhibit 11, I believe?

11 A Yes.

12 Q And if you don't mind turning to -- in
13 the bottom right corner, it ends with 598, and it
14 is four pages from the back.

15 A Yeah. Is that the Services and Fees
16 again?

17 Q Yes, uh-huh.

18 A Okay.

19 Q Paragraph 1 is the Company-sponsored
20 Speaker Program, which is checked "yes" now, and
21 it says, "Consultant shall make such
22 presentations on two occasions. The presentation
23 will review pelvic floor repair and stress
24 urinary incontinence."

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1 Do you see that?

2 A Yes.

3 Q And do you -- do you have a memory as
4 to what those speaker programs would have
5 involved?

6 A Those were where I was invited to go
7 out of town and make a presentation to a
8 physician group.

9 Q And looks like that, for each such
10 speaking engagement, you were paid \$3,000 per
11 eight-hour day plus out-of-pocket expenses.
12 Correct?

13 A Correct.

14 Q Okay. And it also states in that
15 paragraph that there were two occasions that you
16 were to do that, which would obviously be \$6,000.
17 Do you think that you would have maxed out that
18 6,000?

19 A Gosh, I -- you know, I don't know.

20 I -- I mean, when I think back on it, I can only
21 think of a couple of occasions where I went out
22 of town.

23 Well, yeah. Maybe two or three or four
24 where I actually went out of town to do something

1 like that. So --

2 MR. BARTON:

3 Over all the years?

4 THE WITNESS:

5 Yeah, over all the years.

6 MS. WATKINS:

7 Q On those occasions you were paid the
8 \$3,000.00 per day plus out-of-pocket expenses?

9 A I presume, yes.

10 Q And you were still, if you look under
11 paragraph 4, still doing the preceptor work, but
12 in this year it looks like you had 16 occasions,
13 paid at \$3,000.00 per session. Do you see that?

14 A Yeah. I do. I had forgotten that --

15 Q Did you want to --

16 A Yeah. I had forgotten that they went
17 up on --

18 Q Yeah. I guess due to inflation, maybe.
19 Do you think that you would have maxed that out
20 for the 16 sessions at 3,000 per session?

21 A I -- I would guess I did.

22 Q Okay. And if you don't mind turning to
23 the next page --

24 MR. BARTON:

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1 Now, you're not supposed to guess. So
2 if you don't remember, say you don't remember.

3 But don't guess.

4 MS. WATKINS:

5 Q It looks like you were also, under
6 paragraph 8, it states, "Consultant shall perform
7 other services designated below for dollar amount
8 varies per hour," and it includes Faculty
9 Training Meetings and Educational Summit/Forums.
10 Negotiated rate to be no more than the maximum of
11 \$375 rate/per hour."

12 Do you see that?

13 A I do.

14 Q Okay. And I assume those would have
15 been the TVT family of products and the Prolift
16 products. Is that correct?

17 A It would be.

18 Q Okay. And, then, the last line of that
19 page states, "The parties agree that compensation
20 paid to consultant shall not exceed \$60,000 per
21 year except as may be mutually agreed in writing
22 by the parties."

23 Do you think that you would have maxed
24 out that \$60,000 per year in 2010?

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1 A I don't think I -- I don't think I ever
2 got that much. But I -- I don't know for sure.

3 Q Do you have a memory as to the maximum
4 amount per year, when you were working as a
5 consultant for Ethicon, that you would have
6 received?

7 A No, I don't.

8 Q Do you think that at any point you
9 would have received \$60,000 per year from Ethicon
10 working as a consultant?

11 A Like I said, I don't -- I don't -- I
12 don't recall ever receiving that much. That
13 seems like more than --

14 I could be wrong, but I don't remember
15 that.

16 Q Okay. You can set that aside, and
17 we'll go to the last one, which is dated
18 February 1st, 2011.

19 A Yes.

20 Q Okay. And if you don't mind going to
21 that Exhibit A, which in the bottom right corner
22 is -- page is 267.

23 A Okay.

24 Q Again, company-sponsored speaking --

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1 speaker programs is checked, and it states that
2 you shall make presentations on three occasions
3 for \$3,000.00 per eight-hour day plus
4 out-of-pocket expenses.

5 Do you believe that you would have
6 maxed out those three occasions for 2011?

7 A I don't think so.

8 Q Okay. Well, why do you think that's
9 not the case?

10 A I just don't recall doing three
11 out-of-town meetings to -- for educational
12 purposes. I -- I don't -- I don't recall ever
13 doing that. I --

14 When I think back on it, you know, I
15 can -- I can recall maybe three or four times
16 over the course of the entire time that I went
17 out of town to do a presentation.

18 MR. BARTON:

19 And how many years was that?

20 THE WITNESS:

21 Over a period of --

22 MS. WATKINS:

23 Q And, then, under the preceptor portion,
24 it looks like, for the year 2011, "Consultant

Charles Hanes, II, M.D.

1 shall allow such visits on up to 12 occasions and
2 the company shall pay consultant \$3,000 for each
3 session per eight-hour day."

4 Do you believe that you would have done
5 the 12 occasions at \$3,000 per session?

6 A I think so.

7 Q Okay. And, if you don't mind, Doctor,
8 please turn to the next page. Under Paragraph B,
9 it says that your compensation paid to consultant
10 shall not exceed \$51,000 per contract term. Do
11 you believe that you would have maxed out the
12 51,000 in 2011?

13 A I don't think so. I don't think I
14 reached that number.

15 Q Okay. And, then, you mentioned that
16 you were also a consultant with Ethicon in 2012.
17 Do you recall your role -- we cannot find a
18 contract for that. Do you recall your role as a
19 consultant for Ethicon in 2012?

20 A Well, now, I'm not -- I'm not sure if I
21 actually did any consulting in 2012. My -- my
22 recollection is that the preceptor relationship
23 terminated either late in 2011 or early in 2012.
24 And I can't remember.

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1 Q Okay. Is there a reason why it
2 terminated?

3 A Well, that was when the products, the
4 Prolift products were removed from the market.
5 And by that time, there really wasn't any need
6 for training on the TVT products because they had
7 been so universally adopted. It'd become
8 products of choice and, you know, in a lot of
9 people's view, the gold standard.

10 Q Okay. And I should have asked you this
11 at the beginning of this line of questioning, but
12 what led to you becoming a consultant for
13 Ethicon?

14 A I'm sorry. What?

15 Q What led to you becoming a consultant
16 for Ethicon? Like, how did that come about?

17 A That came about because, very early on
18 after the introduction of the product, I -- I
19 got -- I can't remember exactly, but I think that
20 I went to a meeting and I was -- was very
21 infatuated with the concept, and I ended up going
22 to a company-sponsored cadaver lab for training
23 purposes, and I quickly embraced the product
24 because at that point in time the incontinence

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1 procedures I was doing were the Burch procedures
2 through open incision, and I also had done a few
3 laparoscopic Burches.

4 But -- but the simplicity of the TVT,
5 the midurethral sling, that whole concept was so
6 appealing because of being minimally invasive,
7 and the preliminary data that was coming out of
8 Europe that was available to us was very
9 encouraging in terms of efficacy.

10 And, so, I got on board pretty quickly.
11 And, because of that, I -- and I -- I was asked
12 and I expressed an interest in becoming a
13 preceptor just because I believed so much in the
14 product.

15 As soon as I began using it, the
16 feedback I was getting from my patients totally
17 reinforced all of the good reports that I was --
18 I was hearing. And, so, I was pretty
19 enthusiastic about it.

20 Q Okay. And have you been a consultant
21 for any other transvaginal mesh company?

22 A I have not.

23 Q Okay. If you guys are okay with it,
24 we've been going about an hour and 20 minutes.

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1 Maybe we can take a 5-minute break for the
2 bathroom?

3 A Sure.

4 Q Okay. I'll be back in five.

5 (BRIEF RECESS.)

6 MS. WATKINS:

7 Q Okay, Doctor. We're back on the record
8 from a short break. And I asked you some
9 questions at the beginning of the deposition
10 about a supplemental general materials list that
11 I was served with a couple of days ago. And, as
12 we sit here today, it's my understanding that you
13 have not seen that. Is that correct?

14 A Oh, no. I've seen the general
15 materials list.

16 Q Okay. I received a supplemental one.

17 A Oh, the supplemental. Yeah. No, I --
18 I don't think I've seen that.

19 Q Okay. So, as we sit here today, your
20 general materials list is your reliance list;
21 correct?

22 A Correct.

23 Q And does it include everything that you
24 are relying on in forming your general causation

Charles Hanes, II, M.D.

1 **opinions in this litigation?**

2 A It does.

3 Q **Did you prepare that reliance list?**

4 A No, I did not.

5 Q **Do you have an understanding as to who**
6 **prepared it?**

7 A I believe it was prepared by Butler
8 Snow, but I -- I'm not certain.

9 Q **Okay. Is it your understanding that**
10 **Butler Snow picked the materials listed on the**
11 **reliance list?**

12 MR. BARTON:

13 What was the question?

14 A Say -- repeat that, please.

15 MS. WATKINS:

16 Q **Yes.**

17 **Do you have an understanding as to who**
18 **picked the materials listed on the reliance list?**

19 A I don't -- I don't know who -- who was
20 responsible for that.

21 Q **Have you reviewed every item on the**
22 **materials list?**

23 A No.

24 Q **Did you review any Ethicon corporate**

Charles Hanes, II, M.D.

1 documents in forming your general causation
2 opinions?

3 A I did not specifically review any
4 Ethicon documents.

5 Q Did you review any depositions in
6 forming your general causation opinions in this
7 litigation?

8 A I reviewed some of the other general
9 reports, general expert reports on these
10 products. I did.

11 Q Okay. Did you review any deposition
12 testimony?

13 A In preparing these documents, no, I did
14 not.

15 Q Okay. Bear with me, Doctor.
16 Did you ask to see any Ethicon
17 corporate documents before preparing your general
18 causation reports?

19 A No.

20 Q Did you ask to review any depositions
21 of any corporate witnesses before preparing your
22 reports?

23 A No.

24 Q Have you at any point reviewed any

Charles Hanes, II, M.D.

1 medical literature that has called into question
2 the safety of Ethicon transvaginal mesh products?

3 A I've reviewed tons of literature that
4 have referred to the products, as well as
5 potential problems and complications, just in the
6 course of my career, yes.

7 Q Okay. Have you reviewed any medical
8 literature that indicates that, after a proper
9 implantation, the mesh used in Ethicon's TVT-O
10 and Prolift products can degrade?

11 A I've seen claims to that effect, but I
12 have not --

13 Well, I've seen some of the plaintiffs'
14 expert witnesses' reports that have alleged that.
15 I -- in my personal experience, I -- I don't
16 believe any of that. It just doesn't hold water
17 with me.

18 Q Okay. So, just so that I have an
19 understanding, as far as medical literature, have
20 you seen any medical literature indicating that
21 Ethicon's mesh can degrade after a proper
22 implantation?

23 A No, I have not.

24 Q Have you seen any medical literature

Charles Hanes, II, M.D.

1 indicating that a properly placed Ethicon mesh
2 product can rope or curl after implantation?

3 A I can't say that I've seen any
4 literature that has said that.

5 Q Have you seen any medical literature
6 indicating that a properly placed Ethicon mesh
7 product can shrink or contract after
8 implantation?

9 A You know, I can't specifically recall
10 that. As I mentioned earlier, those were
11 certainly points of discussion. But I -- I can't
12 recall a specific article, for example, that
13 would have elaborated on that.

14 Q Okay. Have you reviewed any medical
15 literature indicating that a properly placed
16 Ethicon mesh product can migrate after
17 implantation?

18 A No.

19 Q Have you seen any medical literature
20 indicating that a properly placed Ethicon mesh
21 product can bunch up after implantation?

22 A No.

23 Q And only two more. Have you seen any
24 medical literature indicating that a properly

Charles Hanes, II, M.D.

1 placed Ethicon mesh product can harden or stiffen
2 after implantation?

3 A No.

4 Q Have you seen any medical literature
5 indicating that a properly placed Ethicon mesh
6 product can fray after implantation?

7 A No.

8 Q Switching gears slightly, do you know
9 whether the mesh used for the TVT line of
10 products is mechanical cut, laser cut, or both?

11 A Yes.

12 Q Okay. What is your understanding as to
13 that?

14 A Well, the mechanical cut is -- is,
15 like, cut with scissors or a knife; whereas,
16 laser cut uses a laser. The mechanical cut has
17 edges that aren't necessarily intact. They may
18 have loose ends on the edges. Whereas, the laser
19 cut is -- it doesn't. All the edges -- each
20 little fiber comes together. And there are
21 properties of -- the laser cut's generally a
22 little bit stiffer in its physical properties.
23 But those are the main things that stand out to
24 me.

Charles Hanes, II, M.D.

1 Q Do you have an understanding as to
2 whether there's any difference with respect to
3 the risks associated with a mechanical cut versus
4 laser cut?

5 A I am not aware, and I don't believe
6 there are any difference in risks.

7 Q And if I were to ask you the same thing
8 with respect to the Prolift product, would your
9 answers be the same?

10 A Yes.

11 Q Okay. Have you reviewed any Ethicon
12 corporate documents indicating that physicians
13 reported to Ethicon that its mechanical-cut mesh
14 had properties similar to a Scotch Brite pad?

15 A I haven't seen anything to that effect.

16 Q Okay. Have you reviewed any medical
17 articles that have discussed the edges of the TVT
18 and Prolift mesh being abrasive and sharp?

19 A Say the question again, please.

20 Q Sure.

21 Have you reviewed any medical articles
22 that have discussed the edges of the TVT and
23 Prolift mesh being abrasive and sharp?

24 A I have not seen any medical literature

Charles Hanes, II, M.D.

1 that says that.

2 Q Okay. I want to switch gears a little
3 bit and talk about your own use of transvaginal
4 mesh products. Over the course of your practice,
5 what transvaginal mesh products have you used to
6 treat stress urinary incontinence and pelvic
7 organ prolapse in women?

8 A I've used the Ethicon products;
9 specifically, the retropubic TVT, the TVT EXACT,
10 the TVT-O, the TVT ABBREVO. I used the TVT SECUR
11 briefly.

12 And then I have used some of the other
13 products. Like, I believe I tried the
14 single-incision AMS product. And I can't
15 remember the brand name of that. But I didn't --
16 I didn't like it. I -- I may have --

17 And, then, I am currently using a
18 product by Coloplast that's called the Altus
19 midurethral sling.

20 Q Okay. And have you used any
21 transvaginal mesh product to treat pelvic organ
22 prolapse?

23 A I've used the Prolift products, all of
24 the Prolift products, anterior, posterior, total,

Charles Hanes, II, M.D.

1 Prolift, Prolift + M. I've used the Boston
2 Scientific Uphold. I have tried the Boston
3 Scientific -- I think it was the Pinnacle, maybe.

4 But, again, I -- any deviation I made
5 from the Prolift products was really just
6 experimental to see whether or not I felt like
7 they were as good as the Prolift products. And,
8 so, I --

9 But that was the extent of it. I
10 thought the Prolift products were excellent
11 products and did what I expected them to do and
12 gave me the results that I expected them to give.

13 Q And when was the last time you
14 implanted a product from the TVT line of
15 products?

16 A Probably within the last several
17 months.

18 Q And you mentioned that you currently
19 implant the Coloplast Altus. Is that your first
20 choice currently in treating stress urinary
21 incontinence in women --

22 A It is.

23 Q -- currently?

24 A Yes.

Charles Hanes, II, M.D.

1 Q Why is that?

2 A It's because it's a single-incision
3 sling, which I had totally sworn off until it
4 came on the market, because I had tried
5 periodically -- I tried the TVT SECUR, I tried
6 this AMS product, and I didn't like them because
7 they were not adjustable. In other words, you
8 could insert them and tighten them up, but if you
9 determined that they needed to be looser, you
10 couldn't loosen them without taking them out.

11 And this Altus sling is a totally
12 adjustable midurethral sling that's in the same
13 conformity as a transobturator approach, and you
14 can tension it or loosen it. So it has
15 everything I like, and it's minimally invasive.
16 It's -- I had --

17 My product of choice had become the TVT
18 ABBREVO, which I think is an excellent product,
19 as I also think the TVT EXACT is an excellent
20 product. But -- but the Coloplast, because of
21 its even less-invasive properties, is why I have
22 embraced it.

23 Q Okay. In your current practice, what
24 treatment --

Charles Hanes, II, M.D.

1 Well, strike that.

2 In your current practice, what surgical
3 treatment options do you use to treat pelvic
4 organ prolapse?

5 A I use a variety. I use -- if it's a
6 reconstructive procedure, then I -- the native
7 tissue repairs that I do are the anterior and
8 posterior colporrhaphies, the apical suspension
9 procedures or uterosacral ligament suspension,
10 and sacrospinous ligament suspension.

11 And then I do, if I feel like mesh is
12 appropriate, then I do a sacrocolpopexy that I do
13 transvaginally.

14 Q Okay. Do you also do abdominal
15 sacrocolpopexies?

16 A I don't.

17 Q Okay. Why is that?

18 A Because the vaginal sacrocolpopexy is
19 better.

20 Q Okay. And can you explain why it's
21 better?

22 A Yeah. That's a very biased statement.
23 But it, in my opinion, it's -- it is better
24 because it's a more direct, less invasive

Charles Hanes, II, M.D.

1 procedure, shorter operating times, less
2 morbidity, and gives full access to the anterior
3 and posterior compartments, as well as the apex,
4 so that a concurrent anterior/posterior repair
5 becomes a natural part of the procedure.

6 Whereas, with the abdominal approach, most
7 people, if they need an additional rectocele
8 repair, for example, they would do their
9 abdominal colpopexy and then come below and do a
10 separate incision for the rectocele repair. So
11 that --

12 That's pretty much my answer. I mean,
13 I think -- I think it's a superior operation.

14 Q Okay. And do you, out of those
15 treatment options, do you consider one of them to
16 be the gold standard for the treatment of pelvic
17 organ prolapse in women?

18 A Well, I think your question needs to be
19 more specific as to where the prolapse is. I
20 mean, if it's --

21 I don't know if you want to specify. I
22 mean, the heart of prolapse repair is the apex.
23 And I -- I presume that you're comfortable with
24 that. I mean, you can do anterior and posterior

Charles Hanes, II, M.D.

1 repair, and everybody does. But, you know, if
2 the apex is not well suspended, then your
3 repair's gonna fail.

4 So, in my opinion, the way I would
5 answer your question is limiting it to apical
6 repairs, apical suspensions. And I think the
7 gold standard is universally recognized as the
8 sacrocolpopexy.

9 Q Okay. And is that treatment option as
10 effective as the Prolift product?

11 A I think it's as effective, yes.

12 Q And is it as safe as the Prolift
13 product?

14 A I think that they're all safe,
15 relatively safe. I mean, you know, every
16 operation has its peculiarities, and -- but I --
17 in my -- in my hands and in my experience,
18 they're all -- the safety profile is very
19 acceptable.

20 Q Okay. Are there risks associated with
21 the Prolift product that are not associated with
22 the sacrocolpopexy?

23 A You know, that's a --

24 Yeah. I think every operation has

Charles Hanes, II, M.D.

1 peculiarities, specific nuances that may make its
2 risks a little bit different. But, all in all, I
3 would say the risks are very comparable between.

4 Q Hello?

5 A I -- you want me to go a little bit
6 further into that?

7 Q Oh, no. I'm sorry. I didn't know if
8 the phone cut out. I just wanted to make sure
9 you were done with your answer, Doctor.

10 A So I -- I think that, you know, the
11 risks associated with Prolift are risks that are
12 pretty much associated with any -- with the
13 sacrocolpopexy, for example. I think -- I think
14 they're very comparable.

15 In fact, actually, let me -- let me
16 back up a little bit. I think that in today's
17 world, and, actually, in the world that we were
18 in during those years of Prolift, the abdominal
19 sacrocolpopexy was frequently done as an open
20 procedure. The laparoscopic approach was done by
21 those who were well trained and able to do
22 laparoscopic -- complex laparoscopic surgery with
23 the knot tying. The robot hadn't really come
24 into play.

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1 So I would say that the large majority
2 of sacrocolpopexies at that point in time were
3 done as -- through open incisions. And,
4 therefore, the morbidity associated with that was
5 significantly higher -- significantly higher --
6 than the Prolift procedures.

7 Prolift, because it's minimally
8 invasive compared to the sacrocolpopexy, had a
9 much lower morbidity.

10 Q Okay. Is a risk associated with
11 Prolift that is not associated with the
12 sacrocolpopexy mesh erosion?

13 A No. You could have mesh erosions with
14 sacrocolpopexy, too.

15 Q Okay.

16 A Yeah. That's a very accepted risk.

17 Q Okay. In your current practice, we
18 talked about some of the transvaginal mesh
19 treatment options you use to treat stress urinary
20 incontinence, but do you have any other treatment
21 options that you use to treat stress urinary
22 incontinence?

23 A I occasionally will do a Burch
24 procedure, but I probably don't do more than

Charles Hanes, II, M.D.

1 one -- one a year, if that.

2 Q Is the Burch procedure a safe surgical
3 treatment option to treat stress urinary
4 incontinence in women?

5 A It's -- well, it's -- I mean, when you
6 say "safe," it -- it has its own set of potential
7 complications. It's much more invasive than the
8 midurethral sling, and, because of that, it's not
9 as safe, I guess --

10 I mean, if safe includes increased
11 morbidity, which, in my mind, it does, then I
12 would say it's not as safe as a midurethral
13 sling.

14 Q But, just generally speaking, is it a
15 safe procedure that you feel comfortable using to
16 treat stress urinary incontinence in your
17 patients even though it's --

18 A Yes.

19 Q -- infrequently?

20 Okay. Do you keep a patient registry
21 for the patients in whom you have implanted
22 transvaginal mesh products?

23 A No.

24 Q So is it fair to say that you can't say

Charles Hanes, II, M.D.

1 with accuracy what your complication rates are
2 with respect to the transvaginal mesh products
3 that you have implanted?

4 MR. BARTON:

5 Object to the form.

6 A Yeah. I -- I would not be able to
7 hazard a guess on what my complication rate is.
8 I think it's -- it's a -- you know, it would be
9 considered a very acceptable rate, but I -- I
10 don't know specifically what it would be.

11 MS. WATKINS:

12 Q Okay. In your practice, do you perform
13 mesh excision procedures?

14 A I do.

15 Q Okay. And do you perform mesh revision
16 procedures?

17 A I do.

18 Q And just for the sake of the jury, can
19 you explain the difference between an excision
20 procedure and a revision procedure?

21 A Certainly. A revision procedure would
22 be a procedure where there may be a --

23 Two, I guess, cases that would be
24 representative would be a small mesh exposure in

Charles Hanes, II, M.D.

1 which case you could excise that exposure and
2 then close the tissue back over that defect and
3 leave the bulk of the mesh to do the job and
4 provide the function for which it was implanted;
5 whereas, a --

6 What was the term you used for --

7 Was it a --

8 **Q A revision?**

9 **A Versus --**

10 **Q Excision.**

11 **A Excision.** So the excision would be
12 where the product was being removed or at least a
13 significant part of the product was being
14 removed. And the most notable examples of that
15 would be if there were -- for example, with
16 the -- with the midurethral sling, if the sling's
17 too tight and the patient's complaint is
18 difficulty emptying her bladder, then one of the
19 things that we do is just go in and transect the
20 sling, which loosens it a little bit, but it
21 leaves the bulk of it -- leaves the entirety of
22 it in, but just loosening it that way usually
23 provides relief to where they're voiding normally
24 but preserves the function of preventing stress

Charles Hanes, II, M.D.

1 incontinence.

2 Q Okay. And do you have an estimate as
3 to how many mesh excision procedures you have
4 performed?

5 A I don't.

6 Q Do you think it's over a hundred?

7 A Yes.

8 Q Over two hundred?

9 A Well, probably. But I -- you know,
10 over the course of years, I really don't have an
11 accurate way to estimate that.

12 Q Okay. But you think it's --

13 A Certainly over a hundred.

14 Q Okay. And what about mesh revision
15 procedures? Do you have an estimate as to how
16 many of those you've performed?

17 A That would be over a hundred as well.

18 Q Okay. And do you believe that you have
19 excised and revised mesh from both the TVT line
20 of products and the Prolift line of products?

21 A I have.

22 Q Okay. And what are the reasons, in
23 your practice, why you've recommended mesh
24 excision and revision procedures to your

Charles Hanes, II, M.D.

1 patients?

2 A Well, it goes back to my answer
3 earlier. There are a variety of reasons. It can
4 be difficulty voiding. It could be mesh
5 exposure. It could be discomfort or pain with
6 intercourse. I think those would be -- those --
7 that would represent the majority of reasons.

8 Q Okay. And this is a little bit of a
9 similar question, and I apologize if it seems
10 somewhat repetitive, but what complications
11 caused by transvaginal mesh have you seen in your
12 practice?

13 A Are you referring to operative
14 complications or postoperative complications?

15 Q Postoperative complications.

16 A Okay. So I would say those primarily
17 fall into those categories that I just said,
18 either mesh exposure, voiding dysfunction, which,
19 again, is just difficulty urinating because the
20 -- a sling may be in too tight, or pain --
21 usually pain with intercourse.

22 Q Have you, in your practice, seen just
23 pelvic pain, separate and apart from pain with
24 intercourse, as a complication associated with

Charles Hanes, II, M.D.

1 transvaginal mesh?

2 A I have, yes.

3 Q Okay. And you mentioned voiding
4 dysfunction due to the product's being too tight.

5 Is it your opinion that in those cases that is
6 surgeon error, or can the product become too
7 tight after implantation?

8 A I think it's mostly where it was
9 probably put in a little bit too tight. I think
10 it's -- I think that's the usual. I don't
11 think -- I'm not sure that I've seen -- or, if I
12 have, it's been very, very rare where somebody's
13 had a sling in for a period of time that's worked
14 optimally and then suddenly had a voiding
15 difficulty.

16 Q Do you agree that a woman can develop
17 mesh complications five or more years after
18 implantation?

19 A I think the literature says -- it
20 supports that mesh erosions can occur over time,
21 and I think that's usually related to other
22 factors, like vaginal atrophy. It can be related
23 to -- well, I guess vaginal atrophy is probably
24 the biggest one. And I think smoking also is a

Charles Hanes, II, M.D.

1 risk factor for delayed exposures. So I think
2 there are some variables that enter into that.

3 Q Okay. Do you agree that a woman can
4 develop mesh complications ten or more years
5 after implantation?

6 A Well, the time frame, I don't -- I
7 don't think -- I'm not aware that there's
8 anything saying what number of years. I mean, I
9 think it can happen probably any time. Again,
10 it's a function of things that, in my -- in my
11 mind, are not mesh-related. They're more related
12 to other things, like vaginal atrophy.

13 Q Do you agree that it is difficult to
14 fully remove a transvaginal mesh device from a
15 woman's body?

16 A I think it's -- I think it's a surgical
17 procedure that sometimes can be very difficult.
18 But I think that, in my -- in my hands, I feel
19 very comfortable removing whatever needs to be
20 removed and feel like if I need to remove it, I
21 can get it. You know, it's not like -- it's not
22 like you do an operation and it's suboptimal and
23 that you can't get the mesh that you've gone to
24 get. Sometimes it takes longer, it's more

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1 technically difficult, but I --

2 In other words, I find reports of
3 patients who've had mesh excision procedures
4 that -- where it hasn't been removed. And I
5 think that's a function of an inadequate surgery.

6 But I think that if somebody knows what
7 they're doing and how to do it, that it should be
8 able to be done.

9 Q Okay. Have you ever been able to fully
10 remove a transvaginal mesh device from a
11 patient's body?

12 A I have fully removed on maybe two
13 occasions that I can think of where I actually
14 did it through combined incisions of vaginal and
15 retropubic in one case and vaginal and groin
16 incisions in another case. But those were very
17 unusual, and I -- I find -- I find that that is
18 totally unnecessary. And I think the -- I think
19 that the bulk of opinion from physicians who do
20 this kind of surgery would say you remove that
21 part of the mesh that's in contact with the
22 vagina, and as far as dealing with the arms that
23 go distal to -- to the -- to the vagina, there's
24 no merit in removing that.

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1 Q Okay. With respect to the two
2 procedures in which you fully removed a
3 transvaginal mesh device, would you consider them
4 complicated procedures?

5 A Not -- no, not necessarily. No.

6 Q Okay. Would you consider them complex
7 procedures?

8 A No.

9 Q Okay. Bear with me, Doctor. I'm going
10 through my outline here.

11 Is chronic pelvic pain a risk of the
12 TVT line of products?

13 A Chronic pelvic pain is a risk of any
14 vaginal surgery, any pelvic reconstructive
15 surgery. So it is one of those acceptable risks
16 that goes along with this -- this specialty.

17 Q Is the same true with respect to the
18 Prolift product?

19 A Yes.

20 Q Okay. Are there risks associated with
21 the presence of a properly placed Ethicon
22 transvaginal mesh product within a woman's
23 pelvis? What I mean by that is are there risks
24 associated with the presence of the product

Charles Hanes, II, M.D.

1 separate and apart from the cervical procedure?

2 A Well, I think what you're alluding to,
3 is there a risk of mesh as opposed to no mesh in
4 a surgical procedure? Is that another way of
5 asking that question?

6 Q I think so. I think we're basically on
7 the same page. I guess my question is: Is the
8 presence of the polypropylene mesh from Ethicon's
9 product within a woman's pelvis associated with
10 any risk to the woman, separate and apart from --

11 MR. BARTON:

12 I'm gonna object to the form.

13 A I think -- I think the use of mesh
14 carries its own set of potential problems, which
15 we've alluded to earlier, in that there's a risk
16 of mesh exposure. There's, you know -- there are
17 some inherent risks associated with the use of
18 mesh, yes.

19 MS. WATKINS:

20 Q Okay. And I don't mean to cover ground
21 we've already talked about, but you mentioned
22 exposure. Can that also include erosion into
23 surrounding organs?

24 A It can include that. I've never

Charles Hanes, II, M.D.

1 seen --

2 Well, no. I take it back. I've seen a
3 mesh in the urethra. But I don't think -- I do
4 not think that that was a function of migration
5 of the mesh. I think it was a function of an
6 improper insertion. So --

7 Q Okay.

8 A -- I don't -- I don't believe -- I know
9 that there are reports of mesh in organs and, you
10 know, that's something that can happen. But I
11 think it happens as a result of improper
12 implantation.

13 Q Okay. So do you believe that there
14 are --

15 Well, strike that.

16 Do you believe that a properly placed
17 Ethicon transvaginal mesh product can cause
18 complications for a woman after implantation?

19 A Well, we've talked about that a little
20 bit in that, you know, you asked about delayed
21 erosions down the road. So, yes.

22 Q Okay. Anything aside from delayed
23 erosions?

24 A I think --

Charles Hanes, II, M.D.

1 MR. BARTON:

2 Object to the form.

3 A I think that's the -- the primary one
4 that would be a remote complication, yes.

5 Q Can a properly placed Ethicon
6 transvaginal mesh product cause urinary
7 dysfunction after implantation?

8 A Yeah. Again, I mean, we -- we
9 mentioned that. That would be the reason that we
10 would do a sling revision --

11 Q Okay.

12 A -- where the mesh was inserted and it's
13 too tight.

14 Q Can a properly placed Ethicon
15 transvaginal mesh product cause chronic pelvic
16 pain for a woman?

17 A It can. But, again, I think that that
18 goes back to, a lot of times, to the insertion
19 where it was under too much tension to begin
20 with.

21 Q Okay. Have you reviewed any medical
22 literature that has discussed fibrotic bridging
23 or scar plate formation around transvaginal mesh
24 after it's been implanted?

Charles Hanes, II, M.D.

1 A I'm familiar -- I'm familiar with that,
2 yes. I can't say that I've -- I can't say that
3 I've seen any articles that specifically address
4 that.

5 Q So you've seen it in your practice?

6 A I've seen -- yeah. I've seen patients
7 who have had issues with some --

8 I can't remember what the terminology
9 you used, where --

10 Q I used fibrotic bridging and scar plate
11 formation.

12 A Fibrotic. Yeah. And I think that
13 usually is a function of the mesh being put in
14 under too much tension.

15 Q Okay. And can scar plate that forms
16 around mesh inside a woman's vagina cause chronic
17 pelvic pain?

18 A It can. But, you know, I don't --
19 I'm -- I'm not sold on the scar plate issue. I
20 think that with the large-pore monofilament
21 meshes that are in the Ethicon products, I'm
22 not -- I have not personally seen a scar plate.
23 And, now, I've seen it on other products, but I
24 don't think I've seen that on the Gynemesh or

Charles Hanes, II, M.D.

1 Gynemesh PS.

2 Q Okay. Do you have an understanding as
3 to whether there are differences in the pore size
4 between the mesh for the Ethicon product versus
5 the Coloplast Altus product?

6 A Yeah. I'm aware of that.

7 Q Okay. What is the difference in pore
8 size, if any?

9 A The Ethicon mesh has a considerably
10 larger pore size.

11 Q Than the Altus?

12 A Than the Altus, yeah.

13 Q Okay. And do you have an understanding
14 as to what the pore size of the Ethicon mesh is?

15 A You know, I -- I don't specifically
16 know, but I know that it's greater than 75
17 microns, because that's kind of the -- that's
18 kind of the standard for it becoming a
19 macroporous mesh. And it's considerably larger
20 than 75 microns.

21 Q Okay. Do you have an understanding of
22 the weight of the Ethicon mesh?

23 A It's --

24 MR. BARTON:

Charles Hanes, II, M.D.

1 Object to the form.

2 A It -- you know, that's all --

3 I don't -- I don't know in terms of

4 grams per square meter, which I think is the

5 standard for measurement. But I think it's in

6 the intermediate category between lightweight and

7 heavyweight.

8 MS. WATKINS:

9 Q Okay. And do you have an understanding

10 as to the flexibility or stiffness of the Ethicon

11 mesh?

12 MR. BARTON:

13 Object to the form.

14 A I don't -- I don't know any of the --

15 enough about that to really be able to comment.

16 MS. WATKINS:

17 Q Okay. Have you done any lunch or lab

18 research related to polypropylene?

19 A Have I done any lab research related?

20 Q Yes.

21 A I have not.

22 Q Do you consider yourself an expert on

23 polypropylene?

24 A I -- I consider that I have

Charles Hanes, II, M.D.

1 considerable expertise, based on my experience
2 and based on the multiple laboratory training and
3 educational events that I've been to.

4 Q Okay. But do you agree that you are
5 not an expert in materials science?

6 A I -- again, I would say that I have
7 considerable expertise. I mean, where do you
8 draw the line of being an expert? I don't know
9 where that line would be.

10 Q Okay. Have you reviewed the design
11 specifications for the TVT line of products?

12 A By design specifications, I think I'm
13 very familiar with those, based on the training
14 and the corporate events that I attended. They
15 went into considerable detail about the design
16 aspects.

17 Q Okay. Would the same be true with
18 respect to the Prolift product?

19 A Yes.

20 Q And are you an expert in warnings?

21 A In what?

22 Q Warnings.

23 A Warnings?

24 Q Yes.

Charles Hanes, II, M.D.

1 A Like in the IFU? Are you referring to
2 that?

3 Q Yes.

4 A Yeah, I would say --

5 Again, I mean, I would draw the line.

6 I have considerable expertise because I -- in the
7 course of training doctors, we discuss those
8 repeatedly.

9 Q Okay. Have you ever been --

10 Well, strike that.

11 Have you ever drafted a warning for a
12 medical device or pharmaceutical company's
13 product?

14 A No, I have not.

15 Q Are you an FDA regulatory expert?

16 A I'm not -- I would go back and frame
17 that as I'm very familiar and feel like I have
18 some expertise in FDA dealings. But, again, to
19 say I'm an expert, I don't know where you draw
20 the line on that.

21 Q Okay. Have you personally interacted
22 with the FDA with respect to any medical devices
23 or pharmaceutical products?

24 A No.

Charles Hanes, II, M.D.

1 Q Okay. Have you published any medical
2 literature about any of Ethicon's products?

3 A No.

4 Q Okay. I'm almost done, Doctor, so bear
5 with me here.

6 MS. WATKINS:

7 Lois, do you mind marking as -- I guess
8 it would be Exhibit 13, maybe?

9 THE COURT REPORTER:

10 Yes, ma'am.

11 MS. WATKINS:

12 There's two items of literature there.

13 One it titled "Evaluation and Management of
14 Midurethral Sling Complications."

15 THE COURT REPORTER:

16 Right.

17 MS. WATKINS:

18 If you don't mind marking that as an
19 exhibit and then the ACOG Practice Bulletin as an
20 exhibit and letting me know what those numbers
21 are, I'd appreciate it.

22 THE COURT REPORTER:

23 Okay. In that order, Number 13, and,
24 then, ACOG is 14.

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1 MS. WATKINS:

2 Thanks.

3 (EXHIBITS 13 AND 14 WERE

4 MARKED FOR IDENTIFICATION.)

5 MS. WATKINS:

6 Q Okay. Doctor, we've marked as Exhibit

7 13 an April 2016 article titled "Evaluation and

8 Management of Midurethral Sling Complications."

9 Do you have that in front of you?

10 A I do.

11 Q Okay. Have you seen this document

12 before?

13 A I think I have. I'm pretty certain I

14 have.

15 Q Okay. Did you review it in forming

16 your opinions in this litigation?

17 A I'm not sure if this is one of them

18 that I reviewed in -- specifically in this

19 litigation.

20 Q Do you know whether this is on your

21 reliance list that we've marked as an exhibit

22 here today?

23 A I don't know that.

24 Q Okay. If you don't mind turning to the

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1 second page of that. And I want to look at
2 the -- on the left column, the first full
3 paragraph. I'm gonna read something and ask you
4 whether you agree with that.

5 Are you on the second page, Doctor?

6 A I am.

7 Q Okay. I'm gonna read the
8 paragraph or -- excuse me -- the sentence that
9 starts with "nonetheless."

10 A Okay.

11 Q "Nonetheless, certain complications
12 from midurethral sling surgery are unique to the
13 use of polypropylene mesh. These can include
14 mesh exposure, chronic pelvic pain, and
15 dyspareunia, which are the most common, as well
16 as mesh contracture, organ perforation, and/or
17 neuromuscular injury."

18 Do you agree with that statement?

19 A Um, I don't -- you know, I don't think
20 that those complications are unique to the use of
21 polypropylene mesh. In other words, chronic
22 pelvic pain and dyspareunia is -- is a notable
23 complication of any pelvic reconstructive
24 surgery. Organ perforation, also, and

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1 neuromuscular injury for reconstructive surgery.

2 Q Okay. The next sentence reads: "Other
3 complications may include de novo urgency and/or
4 urgency urinary incontinence, urinary tract
5 infection, and/or urinary obstruction."

6 Do you agree with that sentence?

7 A Well, those are complications that can
8 occur with midurethral slings. But, again, they
9 can occur with other operations that are for the
10 correction of incontinence. And, in fact, I
11 think those complications are probably more
12 frequent with the Burch procedure.

13 Urinary tract infections accompany most
14 every operation in which an in-dwelling Foley
15 catheter was inserted.

16 Urgency incontinence is a frequent
17 accompaniment of any kind of incontinence
18 surgery.

19 So I don't -- I don't think any of
20 those are specific to midurethral sling. They
21 certainly can happen with midurethral sling.

22 Q Okay. If you don't mind turning to the
23 second-to-last page of that document. And in the
24 left-hand upper portion of that, it says

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1 "Conclusions." If you don't mind letting me know
2 when you're there, Doctor, I appreciate it.

3 A Oh, yeah. I've gotcha.

4 Q Okay. Good.

5 The first sentence reads,
6 "Complications from midurethral slings are not
7 rare."

8 Do you agree with that statement?

9 A I think that -- I don't know what the
10 definition of "rare" would be. I mean, there's
11 certainly complications that go along with any
12 surgery. So I don't -- I think that's a vague
13 statement.

14 Q Okay. And, then, two sentences down,
15 it states, "However, if a patient does have
16 post-operative concerns, providers should have a
17 high index of suspicion for mesh-related
18 complications."

19 Do you agree with that statement?

20 A I think that if -- if mesh is used, as,
21 obviously, this is talking about the midurethral
22 sling, so there are certain complications that
23 are specific to mesh, but there are also
24 complications that are -- that accompany any

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1 surgery for the correction of incontinence.

2 So, yeah. I mean, I think you have to
3 be aware of the peculiar mesh-related potential
4 complications and be knowledgeable about those.

5 Q Okay. The next sentence reads, "The
6 management of midurethral sling complications is
7 challenging and may warrant referral for
8 specialist care. Unfortunately, these
9 complications are not always reversible and can
10 be quite debilitating for patients."

11 Do you agree with that statement?

12 A By and large, I --

13 I'd have to break it up. I think that
14 for the general OB-GYN practitioner, I think a
15 lot of them are not comfortable or would not be
16 the right ones to do a mesh excision, a
17 midurethral sling excision.

18 As far as the reversibility, I think
19 that if an adequate excision -- if an excision is
20 indicated and if an adequate excision is
21 performed, in my experience, I'm not -- I'm not
22 convinced that I've ever seen anybody that has
23 not -- where their symptoms have not been
24 reversible.

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1 Q Okay.

2 A I suppose there are --

3 I don't -- you know, I wouldn't want to
4 make that a universal statement. I'm sure there
5 may be exceptions, but -- but I think it's rare.

6 Q Okay. And, Doctor, you can set that
7 one aside, please.

8 And, then, if you don't mind moving on
9 to Exhibit 14, the ACOG Practice Bulletin dated
10 November 2017 --

11 A Uh-huh. Okay.

12 Q -- regarding pelvic organ prolapse.

13 A Yes.

14 Q Do you have that in front of you?

15 A Yes.

16 Q And, Doctor, are you a member of ACOG?

17 A I am.

18 Q Okay. And have you seen this document
19 before?

20 A I have.

21 Q Okay. And are you also a member of
22 AUGS?

23 A I am.

24 Q Okay. If you don't mind turning to, on

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1 the bottom right corner -- I guess it's the only
2 one that has a number on it, it's E243.

3 A Yeah, I'm there.

4 Q Oh, you are. Good.

5 All right. This is under the section
6 that reads "What are the complications of pelvic
7 organ prolapse surgery and how are they managed?"

8 A Yes.

9 Q And I'm gonna read from the second full
10 paragraph under that section and then ask you to
11 agree with some of those sentences.

12 "There are unique complications
13 associated with synthetic mesh when they are used
14 in pelvic organ prolapse surgery. These include
15 mesh contracture and erosion into the vagina,
16 urethra, bladder, and rectum."

17 Do you agree with those statements?

18 A Again, I would -- I would have to
19 disagree with the whole mesh contracture thing.

20 I --

21 In principal, you know, I think it's
22 more accurate to say scar contracture. And that
23 goes back to our discussion earlier. I think
24 once the mesh is in place, within two weeks you

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1 have tissue incorporation into the mesh, and,
2 therefore, the mesh itself can't contract. It's
3 the scar that contracts. And the scar
4 contracture is a function of a surgical incision
5 and not -- and not of the mesh. And that's my
6 opinion and that's my experience.

7 As far as erosions into the vagina,
8 that's, you know, what we talked about earlier
9 with mesh exposure.

10 With POP surgery, I've never seen
11 erosion into the urethra. As I mentioned
12 earlier, I saw a transurethral sling, but I think
13 that was a function of improper insertion. But
14 I've never seen that with the POP surgery. And
15 I've never seen erosion into the bladder or
16 rectum.

17 Again, I think that if -- if that
18 occurs, it more than likely is a function of
19 improper insertion as opposed to migration. I
20 don't -- I do not believe it's possible for mesh,
21 once it's integrated with tissue, to migrate
22 anywhere.

23 Q Okay. Are you familiar with any
24 medical literature indicating that a properly

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1 placed transvaginal mesh product can migrate
2 after implantation?

3 A No. That's what I say. I don't
4 believe that's possible.

5 Q Okay. The next sentence reads, "The
6 rate of mesh erosion is approximately 12 percent
7 after vaginal mesh prolapse surgery."

8 Do you agree with that statement?

9 A I think that's a -- that's a figure
10 that is debatable. I mean, I think there --
11 there are figures that are tossed out, and I've
12 seen figures ranging from 5 percent or even as
13 low as 3 percent in some series. But I think 12
14 percent would be upper limits.

15 Q Do you have any reason to disagree with
16 that number?

17 A Well, I don't know -- you know, I don't
18 know where they got that number. If it's a
19 meta-analysis over a voluminous amount of
20 reports, then I wouldn't refute that.

21 Actually, they reference it as number
22 41, so let's see what it says. So 41 says --

23 Oh, that's -- yeah. That's the
24 systematic review. And I think that was in the

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1 Cochrane database. So, you know, I think that's
2 certainly reputable.

3 But I -- I think that the -- probably
4 the difficulty with that figure is that it
5 doesn't take into account the experience of the
6 users, its multiple users and those with lots of
7 experience and also those with very little. So
8 I, in my opinion, I think that number's high.

9 Q Okay. And, then, the next sentence
10 reads, "When mesh is used for anterior vaginal
11 wall prolapse repair, there is an 11 percent risk
12 of mesh erosion, with 7 percent of these cases
13 requiring surgical correction."

14 Do you have any reason to disagree with
15 those numbers?

16 A Again, I kind of resort to the -- my
17 same answer. I -- I think to say that using mesh
18 in the anterior compartment is gonna subject
19 somebody to 11 percent risk of erosion is
20 probably not an accurate statement if it comes
21 from somebody that's experienced. In fact, I
22 know plenty of doctors who routinely use mesh in
23 the anterior compartment and don't have exposure
24 rates near -- near like that.

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1 So I think when you're taking the --
2 the bulk of the literature and taking all users
3 and coming up with a cumulative number, I'm not
4 gonna say that's not accurate, but I don't think
5 it reflects the experience of experienced users.
6 Otherwise, I don't think they'd be putting it in.

7 Q Okay. And the next sentence reads,
8 "The rate of dyspareunia is approximately 9
9 percent after vaginal mesh prolapse surgery."

10 Do you agree with that number?

11 A I think that -- that may be a good
12 number. But, also, I think that you can find
13 numbers that are comparable and sometimes even
14 higher with other pelvic reconstructive
15 procedures. The posterior repair, for example,
16 is notorious for causing dyspareunia, and that's
17 a native tissue repair. So, yeah.

18 Q Okay. And the last sentence I'm gonna
19 ask you about is what reads: "Multiple
20 procedures often are required to manage
21 mesh-related complications."

22 Do you agree with that statement?

23 A I think that in a lot of cases it has
24 required multiple procedures. But, again, I

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1 would -- I would say in the hands of somebody
2 that's experienced in doing this type of surgery,
3 that it's rare that one procedure is not going to
4 provide the benefit that you're looking for.

5 Q Okay. Doctor, I don't believe I have
6 any additional questions. Thank you for your
7 time. And, again, I'm greatly sorry for being
8 late today.

9 A Well, it's perfectly all right. And I
10 appreciate your being polite over the telephone.

11 MR. BARTON:

12 Can we go off the record for a second,
13 Diane?

14 MS. WATKINS:

15 Sure.

16 (OFF THE RECORD.)

17 EXAMINATION

18 BY MR. BARTON:

19 Q Doctor, in previous examination by
20 plaintiffs' counsel today, she referred you to a
21 sentence in one of your -- the consulting
22 agreements with Ethicon, and the sentence reads,
23 "You shall not make any representation relating
24 to Company's products or to Company's clinical

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1 outcomes unless such representations have been
2 reviewed and approved in advance by Company."

3 Did I read that correctly?

4 A Yes.

5 Q Did that sentence and that part of the
6 consulting agreement, in your recollection, ever
7 come into play in your performance as a
8 consultant for Ethicon? And, if so, how?

9 A I don't think it came into play. I
10 mean, I think -- the way I -- the way I construe
11 that is that in these formal
12 training/preceptor/visiting doctor relationship,
13 that I needed to utilize the materials, the
14 PowerPoint, the IFU, and stay on point with that.
15 It didn't -- it didn't preclude me from going off
16 label at times. If somebody asked me a question,
17 I -- I was free to give them my opinion. And I
18 can't say -- I mean, there were times maybe it
19 wasn't off label.

20 But I never -- I never did deviate from
21 saying my opinion and never, even when company
22 representatives were there, which they frequently
23 were --

24 The representatives were there during

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1 these training sessions a lot of times, and, you
2 know, that was never an issue.

3 MR. BARTON:

4 That's all I have.

5 MS. WATKINS:

6 No questions.

7 (Deposition concluded at 11:55 a.m.)

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1 C E R T I F I C A T E

2 STATE OF ALABAMA)

3 COUNTY OF MOBILE)

4

5 I do hereby certify that the above and
6 foregoing transcript of proceedings in the matter
7 aforementioned was taken down by me in machine
8 shorthand, and the questions and answers thereto
9 were reduced to writing under my personal
10 supervision, and that the foregoing represents a
11 true and correct transcript of the proceedings
12 given by said witness upon said hearing.

13 I further certify that I am neither of
14 counsel nor of kin to the parties to the action,
15 nor am I in anywise interested in the result of
16 said cause.

17 Signed this 15th day of July, 2019.

18

19



LOIS ANNE ROBINSON, RDR

20

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21

ACCR# 352; EXPIRES 9/30/19

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1 E R R A T A P A G E

2

3 I, CHARLES HANES, II, M.D., the witness
herein, have read the transcript of my testimony,
4 and the same is true and correct, to the best of my
knowledge, with the exceptions of the following
5 changes noted below, if any:

6	Page/Line	Change	Reason
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DECLARATION OF WITNESS

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I, the undersigned, declare under penalty

of perjury that I have read the foregoing

transcript, and I have made any corrections,

additions, or deletions that I was desirous of

making; that the foregoing is a true and correct

transcript of my testimony contained herein.

EXECUTED this _____ day of _____,

2019, at _____, _____.

(City)

(State)

CHARLES HANES, II, M.D.